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29 March 1999

Roger Burkhart, Ph.D.
DHHS/PHS/FDA/CDRH
Office of Health and Industry Programs
DMQRP HFZ-240
1350 Piccard Drive
Rockville, MD 20850

Dear Doctor Burkhart:

This letter is in response to the request for comments on the *Compliance Guidance, The Mammography Quality Standards Act Final Regulation Document # 2* which recently appeared on the internet. I understand, from our telephone conversation a couple of weeks ago, that the docket number for submission of comments will not be assigned until the Guidance is published in the Federal Register but in the interim, comments can be sent to you. The comments below relate to 21 CFR 900.12(e)(2)(iv).

Comment #1: Need for appropriate action limits: The Final Rule leaves intact the contrast test action limits of $\pm$ 0.05 OD from the established operating level, a carry over from the phantom-disc method recommended in the 1994 edition of the ACR's *Mammography Quality Control Manual.* However, these action limits are not appropriate for contrast tests using a different test object. Support for this contention can be found in the 1999 edition of the ACR's *Mammography Quality Control Manual* which states .... "The density difference control limits ($\pm$ 0.05) are only applicable when the 4.0 mm acrylic disc is used" (page 185, second paragraph and page 268, third paragraph, copy enclosed).

Comment #2: Need for clarification regarding citations: The Guidance indicates that a facility may conduct the image contrast test using an "added" test object adjacent to the phantom if it **believes it beneficial** to do so. Unless the current action limits are changed, this presents a dilemma for the facility. For example:--

Consider the situation where a facility uses the ACR phantom-disc contrast test and the $\pm$ 0.05 OD action limits. It has been shown previously that this method can fail to detect a 10 kVp change over the range 24-34 kVp. Since no problem is detected, no corrective action is required. The facility is in compliance and is not subject to a citation.

Now consider the situation where the same facility opts to use a different test object positioned adjacent to the phantom. Now even a 1 kVp change can result in a contrast change much larger than $\pm$ 0.05 (see attached graph). The facility must now cease doing mammograms until the source of the"problem" is identified and "corrective" action taken, or be subject to a citation.

Faced with this choice, it is doubtful that many facilities would **believe it beneficial** to use the more sensitive test. In my opinion, subjecting facilities to the possibility of a citation for performing a required QC test in an improved manner is not consistent with the intent of the regulations, nor with Executive Order 12866.

Comment #3: A proposed standard for enforcement: Instead of trying to develop specific numerical action limits for different types of test objects placed in different positions, I suggest that a facility that **believes it beneficial** to conduct the image contrast test using an added test object in a different position (e.g. adjacent to the phantom) should only be required to document that their contrast test method can detect smaller variations in exposure parameters than the ACR phantom-disc method. The data to validate the increased sensitivity of their test could be generated by the facility's physicist or be supplied by manufacturers/vendors of the test object.

I am now in the process of preparing advertising material for marketing the Mammography Beam Quality Monitor and, in order to make sure this material will not be misleading, I need to know if, after April 28, 1999, facilities that conduct the image contrast test using an added test object adjacent to the phantom will still be required to apply the $\pm$ 0.05 action limits? I would appreciate a prompt reply to this question.

Thanking you in advance,

Sincerely,

Benjamin M. Galkin, CRP, FACR
President

Enc

Mammography
Quality Control Manual

Radiologist's Section

Clinical Image Quality

Radiologic Technologist's Section

Medical Physicist's Section

American College of Radiology
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The phantom image background optical density should never be less than 1.20, and the control limits for the phantom image background density should be ±0.20. Thus, in order to have the full ±0.20 density control limits available, the **operating level for phantom image background optical density should be at least 1.40.** Substantially higher phantom image background optical density operating levels may provide improved mammography image quality and avoid underpenetration of dense tissue. However, increasing mAs to achieve higher film optical density will increase the mean glandular dose, and higher average film optical densities will require higher-luminance viewing conditions to see important diagnostic detail.

Generally, the operating level for DD due to the 4.0-mm acrylic disc should be at least 0.40. The DD will vary depending on disc thickness, choice of film, kVp processing conditions, and background image optical density. Higher mAs and background optical density may result in significant increases in density difference even when using the same film, kVp and processing conditions. Once an operating level for density difference is established, control limits are ±0.05 for subsequent phantom images. The density difference control limits are only applicable when the 4.0-mm acrylic disc is used. If a new operating level for background optical density is chosen, then a new operating level for density difference must be established as well.

In addition to assuring that each mammography imaging system produces similar film optical density and DD over time, it is also essential that all mammography units and mammography processors at one facility produce similar film optical densities. It is not acceptable to have one unit or processor producing film optical densities of 1.40 and another producing optical densities of 1.80. Likewise, one should expect each mammography unit and mammography processor at a facility to produce images with similar DD and images of similar image quality.

The mAs noted on the generator readout should not change by more than ±15% for a given density control setting. If the density control setting is changed to accommodate batch-to-batch differences in film speed or as a result of a conscious decision to change the background optical density operating level, then the operating level for mAs should be adjusted appropriately and this action documented in the remarks log (Figure 7B).

RECOMMENDED PERFORMANCE CRITERIA AND CORRECTIVE ACTION

The present criteria for the number of objects to pass the ACR MAP is a **minimum of the four largest fibers, the three largest speck groups, and the three largest masses.** Furthermore, the number of test objects of each group type (fibers, specks, and masses) visible in the phantom image should not decrease by more than one half, assuming the same individual is viewing the images under identical conditions. If a greater change in the number of test objects is noted, then the current image should be compared with the original image and the previous image to determine whether the change is real or if the individual viewing the film has changed his or her criteria.

The phantom image background optical density should never be less than 1.20, and the control limits for the phantom image background density should be ±0.20. Thus, in order to have the full ±0.20 density control limits available, the **operating level for phantom image background optical density should be at least 1.40.** Substantially higher phantom image background optical density operating levels may provide improved mammographic image quality and avoid underpenetration of dense tissue. However, increasing mAs to achieve higher film optical density will increase the mean glandular dose, and higher average film optical densities may require higher-luminance viewing conditions to see important diagnostic detail.

Generally, the operating level for density difference due to the 4.0-mm acrylic disc should be at least 0.40. The density difference will vary depending on disc thickness, the choice of film, kVp, processing conditions, and background image optical density. Higher mAs and background optical density may result in significant increases in density difference even when using the same film, kVp, and processing conditions. Once an operating level for density difference is established, control limits are ±0.05 for subsequent phantom images. The density difference control limits are only applicable when the 4.0-mm acrylic disc is used. If a new operating level for background optical density is chosen, then a new operating level for density difference must be established as well.

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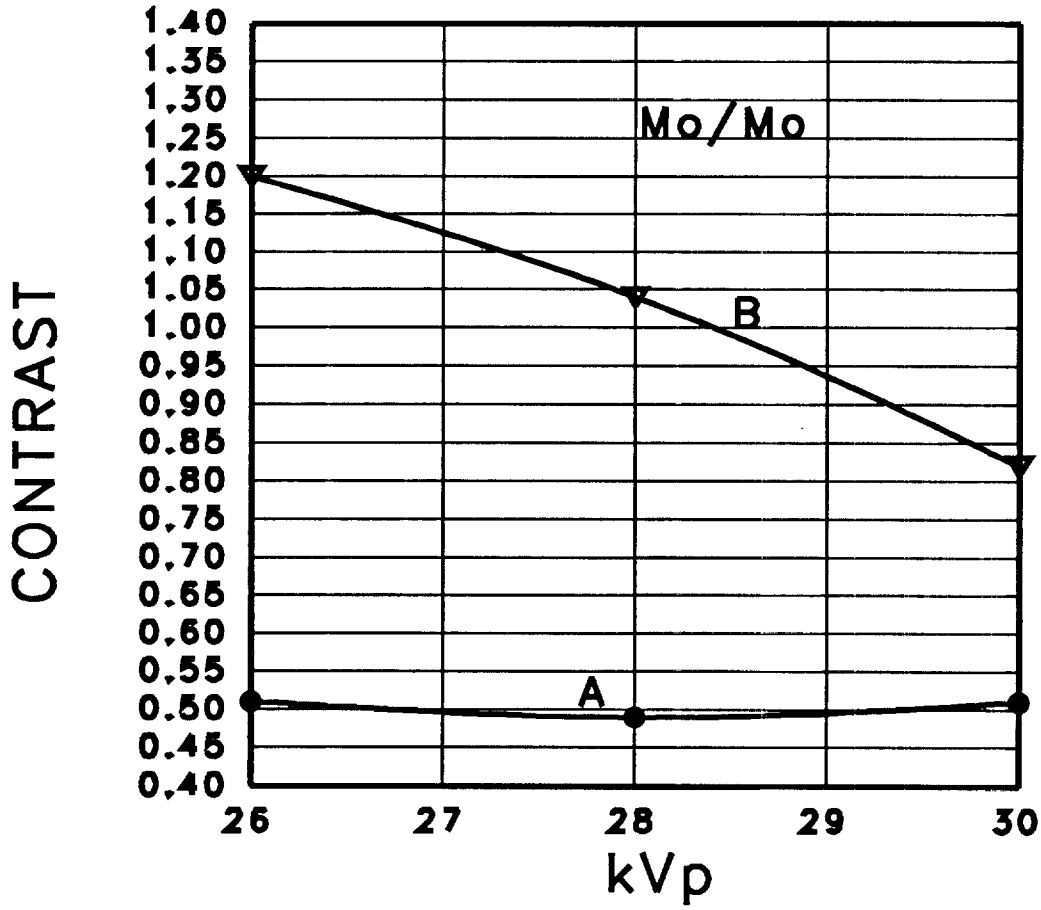
Comparison of Mammography Image Contrast Tests Using Different Methods



A = 4.0 mm acrylic disc on top of breast phantom

B = Mammography Contrast Monitor* adjacent to breast phantom

* Section #1 of Mammography Beam Quality Monitor Mod.B-3

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